PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 08831-007	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CA2004/001851	International filing date *(day/month/year)* 21 October 2004 (21-10-2004)	Priority date *(day/month/year)* 23 October 2003 (23-10-2003)

International Patent Classification (IPC) or national classification and IPC
IPC(7): A61M 16/00, A61H 31/02

Applicant
MAQUET CRITICAL CARE AB ET AL

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [ ] *(sent to the applicant and to the International Bureau)* a total of 12 sheets, as follows:
      [ ] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ,containing a sequence listing and/or tables related thereto, in électronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No.I Basis of the report
   - [ ] Box No. II Priority
   - [X] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [X] Box No. VIII Certain observations on the international application

Date of submission of the demand 17 August 2005 (17-08-2005)	Date of completion of this report 29 September 2005 (29-09-2005)
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Eric Lafontaine (819) 956-9965

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/001851

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (Rules 12.3(a) and 23.1(b))

[ ] publication of the international application (Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

[ ] the international application as originally filed/furnished

[X] the description:

[X] pages	1 to 20		as originally filed/furnished
[ ] pages*		received by this Authority on	
[ ] pages*		received by this Authority on	

[X] the claims:

[ ] pages			as originally filed/furnished
[ ] pages*			as amended (together with any statement) under Article 19
[X] pages*	21 to 32 (claims 1 to 49)	received by this Authority on	17 August 2005 (17-08-2005)
[ ] pages*		received by this Authority on	

[X] the drawings:

[X] pages	1/6 to 6/6		as originally filed/furnished
[ ] pages*		received by this Authority on	
[ ] pages*		received by this Authority on	

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [X] The amendments have resulted in the cancellation of:

[ ] the description, pages

[X] the claims, Nos. 1 to 50

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

[ ] the entire international application

[X] claims Nos. 1 to 21

because:

[X] the said international application, or the said claims Nos. 1 to 21
relate to the following subject matter which does not require an international preliminary examination *(specify):*

The claims are considered to be directed to a method of medical treatment, which the International Search Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

[ ] the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify):*

[ ] the claims, or said claims Nos. are so inadequately supported
by the description that no meaningful opinion could be formed *(specify):*

[X] no international search report has been established for said claims Nos. 1 to 21

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	22 to 49	YES
	Claims	none	NO
Inventive step (IS)	Claims	22 to 49	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	22 to 49	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

I. Novelty:

The combination of features disclosed in claims 22 to 49 are considered to be novel as no reference disclosed all the elements and limitations of the claimed devices. The subject matter of claims 22 to 49 therefore complies with PCT Article 33(2).

II. Inventive Step:

The combination of features disclosed in claims 22 to 49 is not disclosed in the available prior art and involves an inventive step over the available prior art. The subject matter of claims 22 to 49 therefore complies with PCT Article 33(3).

III. Industrial applicability:

The claimed subject matter of claims 22 to 49 is considered to be industrially applicable and thus fulfilling the requirements of PCT Article 33(4).

For the assessment of present claims 1 to 21, which are directed towards a method of medical treatment, under Rule 43bis1(a)(i) and Article 33(4) PCT on whether they are industrially applicable, no unified criteria exists in the PCT.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The incorporations by reference on page 6, line 13 and page 13, line 25 do not comply with Article 5 of the PCT, because the description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art without referring to other documents.

WHAT IS CLAIMED IS:

1. A method of delivering combined positive and negative pressure assist ventilation to a patient, comprising:

applying a positive pressure to the patient's airways to inflate the patient's lungs;

applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and

synchronizing triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.

2. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, comprising:

adjusting levels of the positive and negative pressures to avoid application of excessive positive pressure to the patient's airways and thereby minimize hemodynamic adverse effects.

3. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, wherein applying the positive pressure to the patient's airways comprises:

detecting neural inspiratory activation of the patient; and

applying positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

4. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 3, comprising:

synchronizing triggering and termination of the application of the positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

5. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, wherein applying the positive pressure to the patient's airways comprises:

determining a target level of neural inspiratory activation of the patient;

detecting a level of neural inspiratory activation of the patient;

comparing the detected level of neural inspiratory activation with the determined target level; and

controlling a level of positive pressure applied to the patient's airways as a function of the comparison.

6. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, comprising:

synchronizing triggering and termination of the application of the positive pressure to the patient's airways in relation to the detected level of neural inspiratory activation.

7. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

increasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is higher than the determined target level.

8. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

decreasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is lower than the determined target level.

9. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

maintaining a present level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is equal to the determined target level.

10. A method of delivering combined positive and negative pressure assist ventilation to a patient, comprising:

applying a positive pressure to the patient's airways to inflate the patient's lungs;

applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs, wherein applying a negative pressure comprises adjusting the negative pressure to a value selected from a group consisting of a constant value and a value related to a patient's respiratory related feature; and

synchronizing application of the positive and negative pressures.

11. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

applying a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

12. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

detecting neural inspiratory activation of the patient; and

applying the negative pressure around the patient's ribcage and/or abdomen as a function of the detected neural inspiratory activation.

13. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

determining a target level of an abdominal pressure swing of the patient;

detecting a level of abdominal pressure swing of the patient;

comparing the detected level of abdominal pressure swing with the determined target level; and

controlling a level of negative pressure applied around the patient's ribcage and/or abdomen as a function of the comparison.

14. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of negative pressure applied around the patient's ribcage and/or abdomen comprises:

increasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is higher than the determined target level.

15. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of negative pressure applied around the patient's ribcage and/or abdomen comprises:

decreasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is lower than the determined target level.

16. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of

negative pressure applied around the patient's ribcage and/or abdomen comprises:

maintaining a present level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is equal to the determined target level.

17. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, further comprising applying a constant Negative End-Expiratory Pressure over the abdomen to adjust an end-expiratory lung-volume.

18. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 17, comprising applying the constant Negative End-Expiratory Pressure over the abdomen in combination with inspiratory negative pressure assist ventilation.

19. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 17, comprising applying the constant Negative End-Expiratory Pressure over the abdomen in proportional response to tonic inspiratory muscle activation occurring during expiration.

20. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure comprises obtaining an intrathoracic pressure estimate by measuring an airway pressure deflection during a patient's airway occlusion.

21. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 20, wherein, in case of intrinsic PEEP, obtaining the intrathoracic pressure estimate includes an extrapolation for the period between an onset of electrical activity of the patient's diaphragm activity and an onset of the patient's airway pressure deflection.

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22. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

at least one sensor for detecting at least one patient's respiratory related feature;

a positive pressure ventilator connected to the patient's airways for applying a positive pressure to the patient's airways to inflate the patient's lungs;

a negative pressure ventilator installed on the patient's ribcage and/or abdomen for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and

a controller supplied with said at least one respiratory related feature, and connected to the positive and negative pressure ventilators for controlling operation of said positive and negative pressure ventilators in relation to said at least one patient's respiratory related feature.

23. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, wherein the controller operates the positive and negative pressure ventilators to synchronize triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.

24. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising a sensor of neural inspiratory activation of the patient, the controller being responsive to the neural inspiratory activation detected by the sensor to control the positive pressure ventilator.

25. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

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means for supplying a target level of neural inspiratory activation of the patient; and

a sensor of neural inspiratory activation of the patient;

wherein the controller comprises a comparator of the detected level of neural inspiratory activation with the determined target level to control the positive pressure ventilator in relation to this comparison.

26. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, wherein the controller controls the negative pressure ventilator to apply a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

27. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

a sensor of neural inspiratory activation of the patient;

wherein the controller is responsive to the neural inspiratory activation to control the negative pressure ventilator.

28. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

means for supplying a target level of an abdominal pressure swing of the patient; and

a sensor of a level of abdominal pressure swing of the patient;

the controller comprising a comparator of the detected level of abdominal pressure swing with the determined target level to control the negative pressure ventilator as a function of the comparison.

29. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

first means for applying a positive pressure to the patient's airways to inflate the patient's lungs;

second means for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and

means connected to the first and second pressure applying means for synchronizing triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.

30. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 29, comprising:

means for adjusting levels of the positive and negative pressures to avoid application of excessive positive pressure to the patient's airways and thereby minimize hemodynamic adverse effects.

31. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 29, wherein the first means comprises:

means for detecting neural inspiratory activation of the patient; and

means for applying positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

32. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 31, wherein the synchronizing means comprises:

means for synchronizing triggering and termination of the application of the positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

33. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 29, wherein the first means comprises:

means for determining a target level of neural inspiratory activation of the patient;

means for detecting a level of neural inspiratory activation of the patient;

means for comparing the detected level of neural inspiratory activation with the determined target level; and

means for controlling a level of positive pressure applied to the patient's airways as a function of the comparison.

34. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means comprises:

means for increasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is higher than the determined target level.

35. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means comprises:

means for decreasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is lower than the determined target level.

36. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means comprises:

means for maintaining a present level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is equal to the determined target level.

37. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

first means for applying a positive pressure to the patient's airways to inflate the patient's lungs;

second means for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs, comprising means for adjusting the negative pressure to a value selected from a group consisting of a constant value and a value related to a patient's respiratory related feature; and

means for synchronizing the operation of the first and second pressure-applying means.

38. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means comprises:

means for applying a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

39. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the synchronizing means comprises:

means for synchronizing triggering and termination of the application of negative pressure with triggering and termination of the application of positive pressure.

40. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means comprises:

means for detecting neural inspiratory activation of the patient; and

means for applying the negative pressure around the patient's ribcage and/or abdomen as a function of the detected neural inspiratory activation.

41. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means comprises:

means for determining a target level of an abdominal pressure swing of the patient;

means for detecting a level of abdominal pressure swing of the patient;

means for comparing the detected level of abdominal pressure swing with the determined target level; and

means for controlling a level of negative pressure applied around the patient's ribcage and/or abdomen as a function of the comparison.

42. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

means for increasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is higher than the determined target level.

43. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

means for decreasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is lower than the determined target level.

44. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

means for maintaining a present level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates

that the detected level of abdominal pressure swing of the patient is equal to the determined target level.

45. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, further comprising means for applying a constant Negative End-Expiratory Pressure over the abdomen to adjust an end-expiratory lung-volume.

46. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 45, wherein the constant Negative End-Expiratory Pressure applying means comprises means for applying the constant Negative End-Expiratory Pressure over the abdomen in combination with inspiratory negative pressure assist ventilation.

47. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 45, wherein the constant Negative End-Expiratory Pressure applying means comprises means for applying the constant Negative End-Expiratory Pressure over the abdomen in proportional response to tonic inspiratory muscle activation occurring during expiration.

48. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the means for applying a negative pressure comprises means for obtaining an intrathoracic pressure estimate by measuring an airway pressure deflection during an occlusion of the patient's airway.

49. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 48, wherein, in case of intrinsic PEEP, the intrathoracic pressure estimate obtaining means comprises means for conducting an extrapolation of the intrathoracic pressure estimate for the period between an onset of electrical activity of the patient's diaphragm activity and an onset of the patient's airway pressure deflection.